



PATENT
Attorney Docket 044574-5059-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Albert B. Deisseroth <i>et al.</i>)	
)	
Application No. 09/856,922)	Group Art Unit: 1632
)	
Filed: August 5, 2002)	Examiner: Scott D. Priebe
)	
For: Plastin Promoter Directed Gene Therapy)	

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(c)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(c), Applicant brings to the attention of the Examiner the documents listed on the attached PTO Form 1449. This Information Disclosure Statement is being filed after the events recited in § 1.97(b), but to the undersigned's knowledge, before the mailing date of either a Final Action or a Notice of Allowance. Under the provisions of 37 C.F.R. § 1.97(c), this Information Disclosure Statement is accompanied by a fee of \$180.00 as specified by § 1.17(p).

Submitted herewith is a clean copy of a PTO 1449 form for execution and return by the Examiner. This Information Disclosure Statement is a replacement for the IDS filed on June 9, 2003 and June 30, 2003. Applicants note that document numbers 48, 53, 54 and 65 are newly cited documents and are enclosed herein. The Office has acknowledged receipt of the other documents, thus additional copies of the listed documents have not been submitted herewith.

Applicants note that document numbers 1, 18, 41, 40 and 65 were cited in an International Search Report which issued in a corresponding PCT Application, International Application No. PCT/US99/28613. A copy of the International Search report is attached. In addition, Applicants note that document numbers 4, 38, 39, 40, 53, 54 and 70 were cited in a European Search Report which issued in a corresponding European Application, European Application No. 99961918. A copy of the Supplementary Partial European Search report is also attached.

Applicants respectfully request that the Examiner consider the listed documents and evidence that consideration by making appropriate notations on the attached form. This

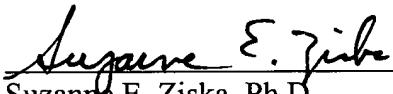
submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute prior art. If the Examiner applies any one of the documents as prior art against any claim in the application, and Applicants determine that the cited document does not constitute prior art under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

Please charge the amount of \$180.00 as set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 50-0310.

Dated: **May 2, 2005**
Morgan, Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Avenue
Washington, D.C. 20004
202-739-3000

Respectfully submitted,
Morgan, Lewis & Bockius LLP


Suzanne E. Ziska, Ph.D.
Registration No. 43,371

INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) PTO Form 1449				Attorney Docket No. 044574-5059		Application No. 09/856,922	
MAY 02 2005 PATENT & TRADEMARK OFFICE				Applicants: Albert B. DEISSEROTH et al.			
				Filing Date: August 5, 2002		Page 1 of 5 Group Art Unit: 1632	

U.S. PATENT DOCUMENTS							
Initial	Document No.	Date	Name	Class	Sub-Class	Filing Date	
	1.	5,360,715	November 1, 1994	Leavitt et al.	435	6	January 10, 1991

FOREIGN PATENT DOCUMENTS							
Document No.	Date	Country	Class	Sub-Class	Translation		
2.	WO 00/33655	June 15, 2000	WIPO				
3.	WO 95/21259	August, 10 1995	WIPO				
4.	WO 94/17182	August, 4 1994	WIPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
5.	Aleman et al. (1999) "Gene therapy for gliomas: molecular targets, adenoviral vectors, and oncolytic adenoviruses" Exp Cell Res., Elsevier, 6277 Sea Harbor Drive, Orlando, FL, USA 252:1-12. Review.
6.	Bailey et al. (1996) "Investigation of alternative prodrugs for use with E. coli nitroreductase in 'suicide gene' approaches to cancer therapy" Gene Therapy, Nature Publishing Group, The Macmillan Building, 4 Crinan Street, London, UK 3:1143-1150
7.	Bergelson et al. (1997) "Isolation of a common receptor for coxsackie B viruses and adenoviruses 2 and 5" Science, American Association for the Advancement of Science 1200 New York Avenue, NW Washington, DC, USA 275:1320-1323
8.	Bergelson et al. (1998) "The Murine CAR Homolog Is a Receptor for Coxsackie B Viruses and Adenoviruses" J. Virology, American Society for Microbiology, 1752 N Street, NW Washington, DC, USA 72:415-419
9.	Berkner (1988) "Development of adenovirus vectors for the expression of heterologous genes" Biotechniques, One Research Drive, Suite 400A, Westborough, MA, USA 6:616-629
10.	Boesen et al. (1994) "Circumvention of chemotherapy-induced myelosuppression by transfer of the mdrl gene" Biotherapy, Springer, 101 Philip Drive, Norwell, MA, USA 6:291-302
11.	Bout et al. (1994) "Lung gene therapy: in vivo adenovirus-mediated gene transfer to rhesus monkey airway epithelium" Human Gene Therapy, Mary Ann Liebert, Inc., 2 Madison Avenue, Larchmont, NY, USA 5:3-10
12.	Bramson et al. (1995) "The use of adenoviral vectors for gene therapy and gene transfer in vivo" Curr. Opin. Biotechnol., Elsevier, 84 Theobald's Road, London, UK 6:590-595
13.	Bridgewater et al. (1995) "Expression of the bacterial nitroreductase enzyme in mammalian cells renders them selectively sensitive to killing by the prodrug CB1954" Eur. J. Cancer, Elsevier, 6277 Sea Harbor Drive, Orlando, FL, USA 31A:2362-2370
14.	Brody et al. (1994) "Direct in vivo gene transfer and expression in malignant cells using adenovirus vectors" Human Gene Therapy, Mary Ann Liebert, Inc., 2 Madison Avenue, Larchmont, NY, USA 5:437-447
15.	Brugger et al. (1997) "Purging of peripheral blood progenitor cell autografts and treatment of minimal residual disease" Stem Cells, AlphaMed Press, 318 Blackwell Street, Suite 260, Durham, NC, USA 15 (Suppl 1):159-165
16.	Buick et al. (1985) "Comparative properties of five human ovarian adenocarcinoma cell lines" Cancer Research, American Association for Cancer Research, Inc. (AACR), 615 Chestnut St., 17th Floor Philadelphia, PA, USA 45:3668-3676
17.	Chen et al. (1996) "Sensitization of human breast cancer cells to cyclophosphamide and ifosfamide by transfer of a liver cytochrome P450 gene" Cancer Research, American Association for Cancer Research, Inc. (AACR), 615 Chestnut St., 17th Floor Philadelphia, PA 56:1331-1340

Examiner:	Date Considered:
-----------	------------------

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) PTO Form 1449				Attorney Docket No. 044574-5059		Application No. 09/856,922	
				Applicants: Albert B. DEISSEROTH et al. Page 2 of 5			
				Filing Date: August 5, 2002		Group Art Unit: 1632	

U.S. PATENT DOCUMENTS							
Initial		Document No.	Date	Name	Class	Sub-Class	Filing Date

FOREIGN PATENT DOCUMENTS							
		Document No.	Date	Country	Class	Sub-Class	Translation

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	18.	Chung et al. (1999) "Use of L-plastin promoter to develop an adenoviral system that confers transgene expression in ovarian cancer cells but not in normal mesothelial cells" Cancer Gene Therapy, Nature Publishing Group, The Macmillan Building, 4 Crinan Street, London, UK 6:99-106					
	19.	Clowes et al. (1994) "Long-term biological response of injured rat carotid artery seeded with smooth muscle cells expressing retrovirally introduced human genes" J. Clin. Invest, 35 Research Drive, Suite 300, Ann Arbor, Michigan, USA 93:644-651					
	20.	Couffinhal et al. (1997) "Histochemical staining following LacZ gene transfer underestimates transfection efficiency" Human Gene Therapy, Mary Ann Liebert, Inc., 2 Madison Avenue, Larchmont, NY, USA 8:929-934					
	21.	Crystal (1999) "In vivo and ex vivo gene therapy strategies to treat tumors using adenovirus gene transfer vectors" Cancer Chemother Pharmacol., Springer Heidelberg, Herstellung, Gertrud Gummert, Tiergartenstr. 17, 69121 Heidelberg, Germany 43 (Suppl):90-99					
	22.	Descamps et al. (1996) "Strategies for cancer gene therapy using adenoviral vectors" J Mol Med, Springer Heidelberg, Herstellung, Gertrud Gummert, Tiergartenstr. 17, 69121 Heidelberg, Germany 74: 183-189					
	23.	Friedlos et al. (1997) "Mustard prodrugs for activation by Escherichia coli nitroreductase in gene-directed enzyme prodrug therapy" J. Med. Chem. American Chemical Society, 1155 Sixteenth Street, NW Washington, DC, USA 40:1270-1275					
	24.	Garcia-Sanchez et al. (1998) "Cytosine deaminase adenoviral vector and 5-fluorocytosine selectively reduce breast cancer cells 1 million-fold when they contaminate hematopoietic cells: a potential purging method for autologous transplantation" Blood, The American Society of Hematology (ASH), 1900 M Street, NW, Suite 200, Washington, DC, USA 92:672-682					
	25.	Gee et al. (1995) "Purging of peripheral blood stem cell grafts" Stem Cells, AlphaMed Press, 318 Blackwell Street, Suite 260, Durham, NC, USA 13 (Suppl. 3):52-62					
	26.	Grossman et al. (1993) "Retroviruses: delivery vehicle to the liver" Curr Opin Genet Dev., Elsevier, 84 Theobald's Road, London, UK 3:110-114					
	27.	Gulati et al. (1992) "Purging in autologous and allogeneic bone marrow transplantation" Curr. Opin. Oncol. , Lippincott Williams & Wilkins, 250 Waterloo Road, London, UK 4:264-271					
	28.	Hammert et al. (1997) "Purging marrow or peripheral blood stem cells for autografting" Curr. Opin. Hematol., Lippincott Williams & Wilkins, 250 Waterloo Road, London, UK 4:423-428					
	29.	He et al. (1998) "A simplified system for generating recombinant adenoviruses" Proc. Natl. Acad. Sci. USA, 500 Fifth Street, NW, NAS 340, Washington, DC, USA 95:2509-2514					
	30.	Hirschowitz et al. (1995) "In vivo adenovirus-mediated gene transfer of the Escherichia coli cytosine deaminase gene to human colon carcinoma-derived tumors induces chemosensitivity to 5-fluorocytosine" Human Gene Therapy, Mary Ann Liebert, Inc., 2 Madison Avenue, Larchmont, NY, USA 6:1055-1063					
Examiner:				Date Considered:			
Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) PTO Form 1449				Attorney Docket No. 044574-5059		Application No. 09/856,922	
				Page 3 of 5			
				Applicants: Albert B. DEISSEROTH <i>et al.</i>		Filing Date: August 5, 2002	
				Group Art Unit: 1632			

U.S. PATENT DOCUMENTS							
Initial		Document No.	Date	Name	Class	Sub-Class	Filing Date

FOREIGN PATENT DOCUMENTS							
		Document No.	Date	Country	Class	Sub-Class	Translation

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	31.	Huber et al. (1991) "Retroviral-mediated gene therapy for the treatment of hepatocellular carcinoma: an innovative approach for cancer therapy" Proc. Natl. Acad. Sci. USA, 500 Fifth Street, NW, NAS 340, Washington, DC, USA 88:8039-8043					
	32.	Huber et al. (1993) "In vivo antitumor activity of 5-fluorocytosine on human colorectal carcinoma cells genetically modified to express cytosine deaminase" Cancer Research, American Association for Cancer Research, Inc. (AACR), 615 Chestnut St., 17th Floor Philadelphia, PA, USA 53:4619-4626					
	33.	Jaffe et al. (1991) "Adenoviral mediated transfer and expression of a normal human α 1-antitrypsin cDNA in primary rat hepatocytes" Clinical Research 39:302 (Abstract)					
	34.	Kianmanesh et al. (1997) "A distant bystander effect of suicide gene therapy: regression of nontransduced tumors together with a distant transduced tumor" Human Gene Therapy, Mary Ann Liebert, Inc., 2 Madison Avenue, Larchmont, NY, USA 10538 8:1807-1814					
	35.	Kiem et al. (1994) "Retrovirus-mediated gene transduction into canine peripheral blood repopulating cells" Blood, The American Society of Hematology (ASH), 1900 M Street, NW, Suite 200, Washington, DC, USA 83:1467-1473					
	36.	Kozarsky et al. (1993) "Gene therapy: adenovirus vectors" Curr Opin Genet Dev. Elsevier, 84 Theobald's Road, London, UK 3(3):499-503					
	37.	Lawrence et al. (1998) "Preferential cytotoxicity of cells transduced with cytosine deaminase compared to bystander cells after treatment with 5-flucytosine" Cancer Research, American Association for Cancer Research, Inc. (AACR), 615 Chestnut St., 17th Floor Philadelphia, PA, USA 58:2588-2593					
	38.	Leavitt (1994) "Discovery and characterization of two novel human cancer-related proteins using two-dimensional gel electrophoresis" Electrophoresis, Weinheim, DE 15:345-357					
	39.	Lin et al. (1993) "Human plastin genes: comparative gene structure, chromosome location, and differential expression in normal and neoplastic cells" J. Biol. Chem. American Society of Biological Chemists, Baltimore, MD, USA 268:2781-2792					
	40.	Lin et al. (1993) "Characterization of the human L-plastin gene promoter in normal and neoplastic cells" J. Biol Chem. American Society of Biological Chemists, Baltimore, MD, USA 268:2793-2801					
	41.	Lin et al. (1997) "The murine L-plastin gene promoter: identification and comparison with the human L-plastin gene promoter" DNA Cell Biology, Mary Ann Liebert, Inc., 2 Madison Avenue, Larchmont, NY USA 16:9-16					
	42.	Manome et al. (1996) "Viral vector transduction of the human deoxycytidine kinase cDNA sensitizes glioma cells to the cytotoxic effects of cytosine arabinoside in vitro and in vivo" Nat. Med., 345 Park Avenue South, New York, NY, USA 2:567-573					
	43.	Mastrangeli et al. (1993) "Diversity of airway epithelial cell targets for in vivo recombinant adenovirus-mediated gene transfer" J. Clin. Invest., 35 Research Drive, Suite 300, Ann Arbor, MI, USA 91:225-234					
Examiner:				Date Considered:			
Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) PTO Form 1449				Attorney Docket No. 044574-5059		Application No. 09/856,922	
				Applicants: Albert B. DEISSEROTH <i>et al.</i> Page 4 of 5			
				Filing Date: August 5, 2002		Group Art Unit: 1632	

U.S. PATENT DOCUMENTS							
Initial		Document No.	Date	Name	Class	Sub-Class	Filing Date

FOREIGN PATENT DOCUMENTS							
		Document No.	Date	Country	Class	Sub-Class	Translation

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	44.	Miller et al. (1993) "Use of retroviral vectors for gene transfer and expression" Meth. Enzymol. Elsevier, 6277 Sea Harbor Drive, Orlando, FL, USA 217:581-599					
	45.	Molpus et al. (1996) "Characterization of a xenograft model of human ovarian carcinoma which produces intraperitoneal carcinomatosis and metastases in mice" Int J Cancer. John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ, USA 68:588-95					
	46.	Moolten FL (1986) "Tumor chemosensitivity conferred by inserted herpes thymidine kinase genes: paradigm for a prospective cancer control strategy" Cancer Research, American Association for Cancer Research, Inc. (AACR), 615 Chestnut St., 17th Floor Philadelphia, PA, USA 46: 5276-5281					
	47.	Mullen et al. (1992) "Transfer of the bacterial gene for cytosine deaminase to mammalian cells confers lethal sensitivity to 5-fluorocytosine: A negative selection system" Proc. Natl. Acad. Sci. USA, 500 Fifth Street, NW, NAS 340, Washington, DC, USA 89: 33-37.					
	48.	Mullen (1994) "Metabolic suicide genes in gene therapy" Pharmac. Ther. Elsevier, 6277 Sea Harbor Drive, Orlando, FL, USA 63:199-207					
	49.	Neering et al. (1996) "Transduction of primitive human hematopoietic cells with recombinant adenovirus vectors" Blood, The American Society of Hematology (ASH), 1900 M Street, NW, Suite 200, Washington, DC, USA 88:1147-1155					
	50.	Park et al. (1994) "Activation of the leukocyte plastin gene occurs in most human cancer cells" Cancer Research, American Association for Cancer Research, Inc. (AACR), 615 Chestnut St., 17th Floor Philadelphia, PA, USA 54:1775-1781					
	51.	Patterson et al. (1995) "Increased sensitivity to the prodrug 5'-deoxy-5-fluorouridine and modulation of 5-fluoro-2'-deoxyuridine sensitivity in MCF-7 cells transfected with thymidine phosphorylase" Br. J. Cancer, Nature Publishing Group, Houndmills, Basingstoke, Hampshire, UK 72:669-675					
	52.	Patterson et al. (1999) "Molecular Chemotherapy for Breast Cancer" Drugs and Aging, Adis Publishers, 770 Township Line Road Suite 300, Yardley, Pennsylvania 19067, USA 14:75-90					
	53.	Peng et al. (1999) "Adenoviral vector mediated chemotherapy sensitization which is tumor specific and kills non dividing cells" Proceedings of the American Association for Cancer Research Annual, 90th Annual Meeting of the American association for Cancer Research, Philadelphia, Pennsylvania, USA, April 10-14, March, 1999 40:597					
	54.	Peng et al. (2001) "The use of the L-plastin promoter for adenoviral-mediated, tumor-specific gene expression in ovarian and bladder cancer cell lines" Cancer Research, American Association for Cancer Research, Inc. (AACR), 615 Chestnut St., 17th Floor Philadelphia, PA, USA 61:4405-4413					
	55.	Roederer et al. (1991) "FACS-gal: flow cytometric analysis and sorting of cells expressing reporter gene constructs" Methods, Elsevier Inc., 360 Park Avenue South, New York, NY, USA 2:248-260					

Examiner:	Date Considered:
-----------	------------------

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
--

INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) PTO Form 1449				Attorney Docket No. 044574-5059		Application No. 09/856,922	
				Applicants: Albert B. DEISSEROTH <i>et al.</i> Page 5 of 5			
				Filing Date: August 5, 2002		Group Art Unit: 1632	

U.S. PATENT DOCUMENTS							
Initial		Document No.	Date	Name	Class	Sub-Class	Filing Date

FOREIGN PATENT DOCUMENTS							
		Document No.	Date	Country	Class	Sub-Class	Translation

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
56.	Roelvink et al. (1998) "The coxsackievirus-adenovirus receptor protein can function as a cellular attachment protein for adenovirus serotypes from subgroups A, C, D, E, and F" J. Virology, American Society for Microbiology, 1752 N Street, NW Washington, DC, USA 10:7909-7915
57.	Rosenfeld et al. (1991) "Adenovirus-mediated transfer of a recombinant α 1-antitrypsin gene to the lung epithelium in vivo" Science, American Association for the Advancement of Science 1200 New York Avenue NW Washington, DC, USA 252:431-434
58.	Rosenfeld et al. (1992) "In vivo transfer of the human cystic fibrosis transmembrane conductance regulator gene to the airway epithelium" Cell, 1100 Massachusetts Avenue, Cambridge, Massachusetts, USA 68:143-155
59.	Salmons et al. (1993) "Targeting of retroviral vectors for gene therapy" Human Gene Therapy, Mary Ann Liebert, Inc., 2 Madison Avenue, Larchmont, NY, USA 10538 4:129-141
60.	Sapi et al. (1998) "Expression of CSF-1 and CSF-1 receptor by normal lactating mammary epithelial cells" J. Soc. Gynecol. Invest., Elsevier Inc., 360 Park Avenue South, New York, NY, USA 5:94-101
61.	Sorscher et al. (1994) Tumor cell bystander killing in colonic carcinoma utilizing the Escherichia coli DeoD gene to generate toxic purines" Gene Therapy, Nature Publishing Group, The Macmillan Building, 4 Crinan Street, London, UK 1:233-238
62.	Spitzer (1996) "Allogeneic peripheral blood stem cell transplantation" J. Infus Chemother 6:33-38
63.	Walsh et al. (1993) "Gene therapy for human hemoglobinopathies" Proc. Soc. Exp. Biol. Med. Society for Experimental Biology and Medicine, 195 West Spring Valley Avenue, Maywood, NJ, USA 204:289-300
64.	Walton et al. (1989) "Molecular enzymology of the reductive bioactivation of hypoxic cell cytotoxins" Int J Radiat Oncol Biol Phys Elsevier Inc., 360 Park Avenue South, New York, NY, USA 16: 983-986
65.	Wang et al. (1996) "Identification of dioxin-responsive genes in Hep G2 cells using differential mRNA display RT-PCR" Biochemical and Biophysical Research Communications, Elsevier, 6277 Sea Harbor Drive, Orlando, FL, USA 220:784-788
66.	Wickham et al. (1993) "Integrins α v β 3 and α v β 5 promote adenovirus internalization but not virus attachment" Cell, 1100 Massachusetts Avenue, Cambridge, Massachusetts, USA 73:309-319
67.	Wickham et al. (1994) "Integrin α v β 5 selectively promotes adenovirus mediated cell membrane permeabilization" J. Cell. Biol. The Rockefeller University Press, 1114 First Avenue, New York, NY, USA 127:257-264
68.	Zhang et al. (1994) "High-efficiency gene transfer and high-level expression of wild-type p53 in human lung cancer cells mediated by recombinant adenovirus" Cancer Gene Therapy, Nature Publishing Group, The Macmillan Building, 4 Crinan Street, London, UK 1:5-13
69.	Zhang (1999) "Development and application of adenoviral vectors for gene therapy of cancer" Cancer Gene Therapy, Nature Publishing Group, The Macmillan Building, 4 Crinan Street, London, UK 6:113-138.
70.	Zhang et al. (2002) "Adenoviral vectors with E1A regulated by tumor-specific promoters are selectively cytolytic for breast cancer and melanoma" Molecular Therapy: The Journal of the American Society of Gene Therapy, American Medical Association, P.O. Box 10946, Chicago, IL, USA 6:386-93

Examiner:	Date Considered:
-----------	------------------

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
--